

Attorney Docket: 00010.05CON

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Joshua D. Rabinowitz, et al. ) Examiner: M. Haghighatian  
Serial No.: 10/792,001 ) Group Art Unit: 1616  
Filing Date: March 03, 2004 ) Confirmation No.: 4247  
For: DELIVERY OF DIAZEPAM THROUGH )  
AN INHALATION ROUTE )

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Applicant calls the Examiner's attention to the patents and publications listed on the attached Form PTO-1449, copies of required documents enclosed, which may be material to examination of the above identified application. The Examiner is requested to make these documents of record.

06/06/2005 JBALINAN 00000095 10792001

03 FC:1806

180.00 DP

TIME OF TRANSMITTAL

This Information Disclosure Statement is being submitted under 37 CFR § 1.97(c). This Statement is filed after three months from the filing date of the national application, after three months from the date of entry into national stage under 37 CFR § 1.491, after the mailing of a first Office Action on the merits, or after the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR § 1.114, but before the mailing date of any of:

- (a) a final action under 37 CFR § 1.113;
- (b) a notice of allowance under 37 CFR § 1.311; or
- (c) an action that otherwise closes prosecution in the application.

This Statement is accompanied by a check for \$180.00 in accordance with 37 CFR

37 CFR 1.8  
CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:  
Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 6/1/05

Signature: Tasha L. Pierce  
Name: Tasha L. Pierce

Best Available Copy

§§1.97(c) and 1.17(p). The undersigned hereby authorizes the charging of any deficiency of fees submitted herewith to Deposit Account No. 19-5117.

Documents listed in the attached Form PTO-1449 and numbered 1, 7, 9-12, 16 and 18-30 are office actions, and the references relied upon therein, issued with respect to co-pending and co-owned applications directed to subject matter that is similar or related to the subject matter of the present invention. Documents listed in the attached Form PTO-1449 and numbered 2-6, 8, 13-15 and 17 are described in the "Background of the Invention" section (page 3, line 23 to page 4, line 19) of priority document U.S. provisional patent application Serial No. 60/294,205 filed May 25, 2001 (attached hereto as Exhibit A). Finally, consistent with our previous disclosures in this application, documents listed in the attached Form PTO-1449 and numbered 31-47 are co-pending and co-owned applications directed to subject matter that is similar or related to the subject matter of the present invention. This updates the list of such applications that were previously disclosed.

The filing of this Information Disclosure Statement shall not be construed as an admission against interest in any manner. This listed patents and publications are believed of interest herein and consideration and citation of as interest by Examiner is respectfully requested.

Respectfully submitted,

Date: June 1, 2005

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to the Bernoulli effect, as described in U.S. Patent No. 5,511,726 to Greenspan et al. The low pressure is used to draw the fluid to be aerosolized out of a second tube. This fluid breaks into small droplets as it accelerates in the air stream. Disadvantages of this standard nebulizer design include relatively large particle size, lack of particle size uniformity, and low densities of small particles in the inhaled air.

Newer liquid aerosol technologies involve generating smaller and more uniform liquid particles by passing the liquid to be aerosolized through micron-sized holes. U.S. Pat. No. 6,131,570 to Schuster et al.; U.S. Pat. No. 5,724,957 to Rubsamen et al.; and U.S. Pat. No. 6,098,620 to Lloyd et al. describe the use of pressure generated by a piston to push fluid through a membrane with laser drilled holes. U.S. Pat. Nos. 5,586,550; 5,758,637; and 6,085,740 to Ivri et al.; and U.S. Pat. No. 5,938,117 to Ivri describe the use of vibration to move fluid through apertures in a shell that are larger on the fluid-coated side.

A limitation of both of these technologies is that they can deliver only very small quantities of liquid solution, e.g., less than 50 microliters, in a single breath. Because the solubility of many drug compounds in water or other solvents suitable for liquid aerosol delivery is low, the total quantity of drug that can be delivered in a single breath is quite small. In addition, the aerosol particle sizes generated by these methods, while small enough to result in substantial alveolar deposition in some cases, result in substantial non-alveolar deposition as well (Heyder et al., *Journal of Aerosol Science* 17:811-825 (1986); Dershwitz et al., *Anesthesiology* 93:619-628 (2000)).

Vaporizing drugs may provide a method of maximizing alveolar delivery and rapidly delivering drugs to target organs. Scented candles and oil lamps are known to volatilize various fragrances and herbal remedies when the wax or oil is heated. For example, U.S. Pat. No. 5,840,246 to Hammons et al. describes an oil lamp that volatilizes insect repellent compositions, deodorizing compositions, medicinal compounds, herbal compositions, and disinfectant compositions. U.S. Pat. No.

5,456,247 to Schilling et al. describes the administration of vaporized sulfamethazine, sulfamethoxazole, sulfamethoxine, and gentamicin by inhalation of the vapor in a treatment chamber. Portable vaporizers and humidifiers that volatilize various compounds are also known. U.S. Pat. Nos. 4,734,560 and 4,853,517 to Bowen describe a vaporizing unit for medications, room deoderizers, room scenting compounds, and room insecticides. U.S. Pat. No. 4,566,451 to Badewien relates to a device that vaporizes medicated liquid. U.S. Pat. Nos. 4,906,417 to Gentry and 3,982,095 to Robinson describe humidifiers that vaporize medication. In the preceding examples, the vaporization of compounds occurs freely into air.

International application WO 94/09842 to Rosen describes a device with an electric heating element that vaporizes a predetermined amount of some agents. U.S. Pat. Nos. 4,917,119 to Potter et al.; 4,941,483 to Ridings et al.; 5,099,861 to Clearman et al.; 4,922,901 to Brooks et al.; and 4,303,083 to Buruss, Jr. also describe hand-held devices that vaporize various medications.

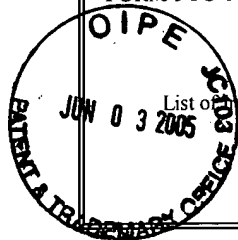
However, the heat required to vaporize a drug often also generates degradation products, which may decrease the efficacy of the thermal vapor and are undesirable to be delivered to the patient. Thus, a method that enhances drug volatilization without the formation of a substantial amount of degradation products is needed.

Therefore, an object of the present invention is to provide a drug with desirable properties for thermal vapor delivery. Such improvement may involve providing a modified drug with enhanced volatility.

Another object of the invention is to provide a thermal vapor for inhalation therapy that does not contain a significant amount of thermal degradation products.

Yet another object of the invention is to provide a form of inhalation therapy where patients can titrate their intake of a drug.

These and other objects of the present invention will become apparent in light of the specific examples and description set forth hereinafter. All publications,



FORM PTO-1449 U.S. DEPARTMENT OF  
COMMERCE PATENT  
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OFFICE

List of Information Cited by Applicant

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ATTY. DOCKET NO.

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SERIAL NO.

10/792,001

APPLICANT

Rabinowitz, et al.

FILING DATE

March 03, 2004

GROUP

1616

U.S. PATENT DOCUMENTS

EXAM. INITIAL		DOCUMENT NUMBER	DATE	NAME	CLS	SUB- CLS	FILE DATE
	1.	4,484,576	11/27/84	Albarda			
	2.	4,566,451	01/28/86	Badewien			
	3.	4,734,560	03/29/88	Bowen			
	4.	4,853,517	08/01/89	Bowen et al.			
	5.	4,303,083	12/01/81	Burruss, Jr.			
	6.	4,906,417	03/06/90	Gentry			
	7.	4,735,217	04/05/88	Gerth et al.			
	8.	5,840,246	11/24/98	Hammons et al.			
	9.	5,743,251	04/28/98	Howell et al.			
	10.	6,090,212	07/18/00	Mahawili			
	11.	5,146,915	09/15/92	Montgomery			
	12.	5,918,595	07/06/99	Olsson et al.			
	13.	4,917,119	04/17/90	Potter et al.			
	14.	4,941,483	07/17/90	Ridings et al.			
	15.	3,982,095	09/21/76	Robinson			
	16.	5,605,146	02/25/97	Sarela			
	17.	5,456,247	10/10/95	Shilling et al.			
	18.	3,949,743	04/13/76	Shanbrom			

FOREIGN PATENT DOCUMENTS

EXAM. INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLS	SUB CLS	TRANS ?
	19.	WO 94/09842	05/11/94	PCT			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	20.	Office Action mailed 12/04/03 for US App. No. 10/057,198 filed 10/26/01 "Method And Device For Delivering A Physiologically Active Compound"
	21.	Office Action mailed 01/12/05 for US App. No. 10/057,197 filed 10/26/01, "Aerosol Generating Device And Method"
	22.	Office Action mailed 06/03/04 for US App. No. 10/057,197 filed 10/26/01, "Aerosol Generating Device And Method"
	23.	Office Action mailed 12/15/03 for US App. No. 10/057,197 filed 10/26/01, "Aerosol Generating Device And Method"
	24.	Office Action mailed 02/27/04 for US App. No. 10/146,080 filed 05/13/02, "Aerosol Forming Device For Use In Inhalation Therapy"

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE</b>  List of Information Cited by Applicant  Page 2 of 2	<b>ATTY. DOCKET NO.</b> 00010.05CON	<b>SERIAL NO.</b> 10/792,001
	<b>APPLICANT</b> Rabinowitz, et al.	
	<b>FILING DATE</b> March 03, 2004	<b>GROUP</b> 1616

U.S. PATENT DOCUMENTS							
EXAM. INITIAL		DOCUMENT NUMBER	DATE	NAME	CLS	SUB- CLS	FILE DATE
	25.	5,649,554	07/22/97	Sprinkel et al.			
	26.	5,592,934	01/14/97	Thwaites			
	27.	6,632,047	10/14/03	Vinegar et al.			
	28.	5,894,841	04/20/99	Voges			
	29.	5,366,770	11/22/94	Wang			
	30.	5,874,481	02/23/99	Weers et al.			
	31.	10/057,198	10/26/01	Lloyd et al.			
	32.	10/302,614	11/21/02	Lu			
	33.	10/146,088	05/13/02	Hale et al.			
	34.	10/280,315	10/25/02	Shen			
	35.	10/322,227	12/17/02	Novack et al.			
	36.	10/442,385	05/20/03	Cross et al.			
	37.	10/719,540	11/20/03	Hale et al.			
	38.	10/750,303	12/30/03	Rabinowitz et al.			
	39.	10/850,895	05/20/04	Damani et al.			
	40.	10/851,429	05/20/04	Hale et al.			
	41.	10/851,883	05/20/04	Hale et al.			
	42.	10/851,432	05/20/04	Hale et al.			
	43.	10/861,554	06/03/04	Cross et al.			
	44.	10/851,018	05/20/04	Hale et al.			
	45.	10/917,735	08/12/04	Hale et al.			
	46.	10/917,720	08/12/04	Hale et al.			
	47.	10/912,417	08/04/04	Bennett et al.			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
EXAMINER	DATE CONSIDERED	
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